

## REMARKS

Claims 32-34 have been canceled in this paper. Claims 1, 3-31, 35, 37, and 39-42 have been amended in this paper. Therefore, claims 1-31 and 35-42 are pending and are under active consideration.

In the outstanding Office Action, the Patent Office sets forth the following election of invention requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31, drawn to a method for determining the biological effect and/or activity of at least one drug, chemical substance, and/or pharmaceutical composition, classified in class 424, subclass 9.1. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.
- II. Claims 32-34 and 36-38, drawn to a use of a method for determining at least one drug, chemical substance, and/or pharmaceutical composition that is biologically effective and/or active, classified in class 424, subclass 9.2. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.
- III. Claim 35, drawn to a biologically effective and/or active drug, chemical substance, and/or pharmaceutical composition, classified in class 424, subclass 1.11. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.
- IV. Claims 39-42, drawn to a method for the treatment of a disease and/or medical condition, classified in class 514, subclass 1. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.

In response to the above election of invention, Applicants respectfully elect Group I, claims 1-31. The foregoing election is, however, made with traverse for the reason that the search and examination of the various groups of claims, particularly, Groups I and IV, would not pose an undue burden on the Patent Office.

In addition to setting forth the above election of invention requirement in the outstanding Office Action, the Patent Office also sets forth in the outstanding Office Action the following election of species requirement:

This application contains claims directed to the following patentably distinct species of the claimed invention:

**First Specie Election Requirement For All Groups:**

Specie A: a biological sample A which is from at least one individual

Specie B: a biological sample A which is from a tissue

Specie C: a biological sample A which is from a cell

Specie D: a biological sample A which is from another biological material not listed above

**Second Specie Election Requirement For All Groups:**

Specie E: a biological sample B which is from at least one individual

Specie F: a biological sample B which is from a tissue

Specie G: a biological sample B which is from a cell

Specie H: a biological sample B which is from another biological material not listed above

**Third Specie Election Requirement For All Groups:**

Group I contains patentably distinct species, namely different means of obtaining the biological sample. If one of these Groups is elected, then please select one or all of the means species (see instant claim 2, for example) so that initial examination of this application may proceed.

**Fourth Specie Election Requirement For All Groups:**

Group I contains patentably distinct species, namely different types of biological sample. If one of these Groups is elected, then please select one or a combination of the biological sample type species (see instant claim 3, for example) so that initial examination of this application may proceed.

**Fifth Specie Election Requirement For All Groups:**

Specie I: biological material which is obtained from healthy individuals only

Specie J: biological material which is obtained from diseased individuals only

Specie K: biological material which is obtained from both healthy and diseased individuals

**Sixth Specie Election Requirement For All Groups:**

Specie L: samples taken before treatment only

Specie M: samples taken during treatment only

Specie N: samples taken after treatment only

Specie O: samples taken before, during, and after treatment

**Seventh Specie Election Requirement For All Groups:**

Group I contains patentably distinct species, namely different methylation DNA site locations. If one of these Groups is elected, then please select one or a combination of methylation DNA regions species (see instant claim 13, for example) so that initial examination of this application may proceed.

**Eighth Specie Election Requirement For All Groups:**

Group I contains patentably distinct species, namely different unwanted side effects related with methylation relevant regions of genes. If one of these Groups is elected, then please select one or a combination of unwanted side effects species (see instant claim 14, for example) so that initial examination of this application may proceed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness or independence of different sample locations, different sample types, different individuals of various health status, different methylation site locations, and different unwanted side effects is because each of these contain distinct entities with structures and functions that differ from other entities. The distinctness or independence of the various obtainment means is because each means involves different processes or steps from the other means. The distinctness or independence of the various treatment timings is because each represents different circumstances from the other timing sets. This divergent subject matter demonstrates the undue search burden if all species were to be initially examined.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claims is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

In response to the above election of species of requirement, Applicants respectfully elect the following: First specie election requirement – Specie A; Second specie election requirement – Specie E; Third specie election requirement – Dissection; Fourth specie election requirement – Histological sample; Fifth specie election requirement – Specie K; Sixth specie election requirement – Specie N; Seventh specie election requirement – complete genes and/or promoters; Eighth specie election requirement - cancer. Claims 1-31 are readable on the elected species.

The above elections are being made with traverse for the reason that that the search and examination of the various species would not pose an undue burden on the Patent Office. For

example, with respect to the first specie election requirement, the different categories of species A-D are not mutually exclusive, e.g., a biological sample that is from at least one individual may also be from a tissue and a biological sample derived from a tissue may also be derived from a cell. Therefore, it is not expected that the search and examination of these different species would be unduly burdensome on the Patent Office. Similar arguments apply to the second specie election requirement. With respect to the third specie election requirement, the Patent Office has failed to explain why it would be unduly burdensome to search and examine all of the sample obtaining techniques listed in claim 2. With respect to the fourth specie election requirement, the Patent Office has failed to explain why it would be unduly burdensome to search and examine all of the different types of biological samples listed in claim 3. With respect to the fifth specie election requirement, the Patent Office has failed to explain why it would be unduly burdensome to search and examine biological materials without regard to whether the materials are obtained from healthy individuals and/or diseased individuals. With respect to the sixth specie election requirement, the Patent Office has failed to explain why it would be unduly burdensome to search and examine samples without regard to when treatment is taken. With respect to the seventh specie election requirement, the Patent Office has failed to explain why it would be unduly burdensome to search and examine samples without regard to where the methylation sites are located. With respect to the eighth specie election requirement, the Patent Office has failed to explain why it would be unduly burdensome to search and examine all unwanted side effects.

In conclusion, it is respectfully submitted that the present application is in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 12, 2004.

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